Willow™ Nasal Pillows System

User Manual

CE 0123

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Willow™ Nasal Pillows System

Thank you for choosing BMC's Willow™ Nasal Pillows System.
The nasal pillows system is light, flexible and quiet. It is designed to minimize contact with your face, thus ensuring that you feel comfortable during therapy. This user guide provides you with the information you need for the correct use of your system.

Intended Use

The Willow™ is intended for single patient reuse by adult patients (>30 kg) prescribed continuous positive airway pressure or Bi-level therapy for use in home, hospitals or clinics.

Medical Information

Note: The Willow™ does not contain latex, PVC, or DEHP materials. If you have ANY reaction to any part of the system, discontinue use and consult your sleep therapist.

WARNING and CAUTION

- This system should be used only with flow generators (CPAP or Bi-level) recommended by your physician or respiratory therapist. It should not be used unless the flow generator is turned on and operating properly. The vent holes should never be blocked.
- **Explanation of the Warning**: Flow generators are intended to be used with special interfaces with connectors which have vent holes (vent holes are located on the elbow) or separate exhalation devices to allow continuous flow of air out of the interface. When the flow generator is turned on and functioning properly, new air from the flow generator will flush the exhaled air out through the attached exhalation port. However, when the flow generator is not operating (eg, power failure), not enough fresh air will be provided through the system, and exhaled air may be re-breathed. In this situation, remove the Willow™ immediately.
- The exhaust vent flow is lower at lower system pressure (see section "Technical Specifications" for Pressure-Flow Curve details). If the system pressure during expiration is too low, there may not be enough exhaust vent flow to completely flush the air delivery hose of exhaled air before the start of the next inspiration.
- Discontinue using the Willow™ if you frequently experience nasal irritation, and consult your physician.
- If oxygen is used with the flow generator, the oxygen flow must be turned off when the flow generator is not operating. Explanation of the Warning: When the flow generator is not in operation, and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the flow generator enclosure. Oxygen accumulated in the flow generator enclosure will create a risk of fire. This warning applies to most types of flow generators.
- Please refrain from smoking while oxygen is in use.

Note: At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, patient breathing pattern, interface selection and the leak rate.

Parts of the Willow™

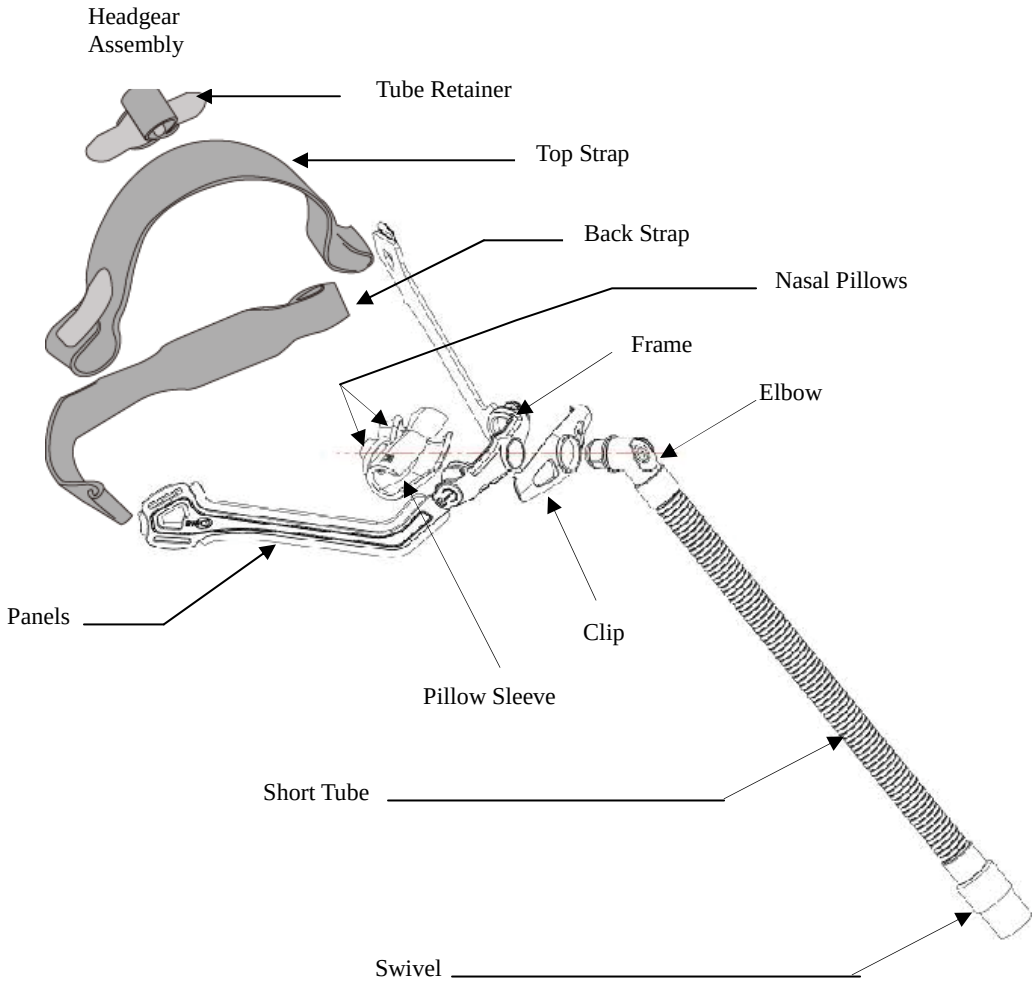
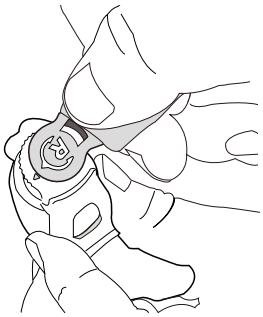


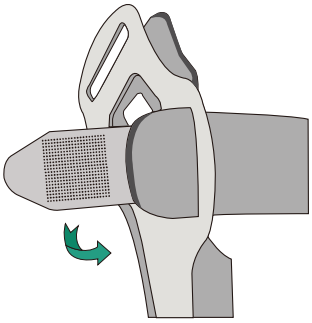
Figure 1 Construction of the Willow™

Fitting the Willow™

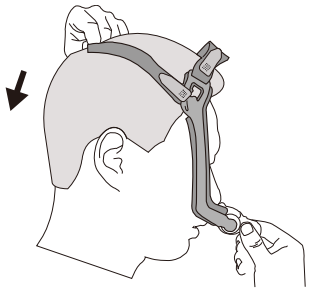


Insert the rectangular block at the smaller end of the panel into the headgear ring on the frame. Make sure the rectangular block is inserted into the correct side.

Rotate the panel to a proper position. Fix the other panel in the same way.

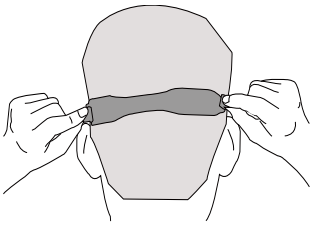


Thread the top and back straps through the gaps in panels separately, then fold back over to secure.

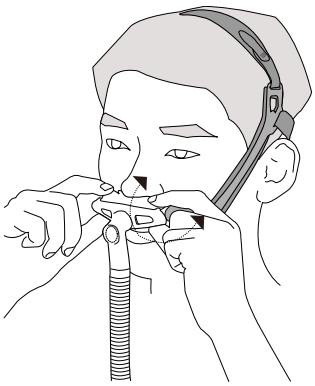


Put the headgear on your head and Insert the nasal pillows into your nostrils. Make sure the top strap passes over the top of your head.

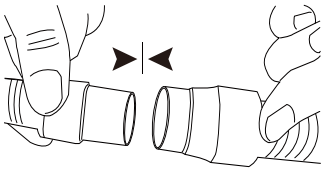
Gently tighten the top strap (overtighting may cause excess pressure on your nose).



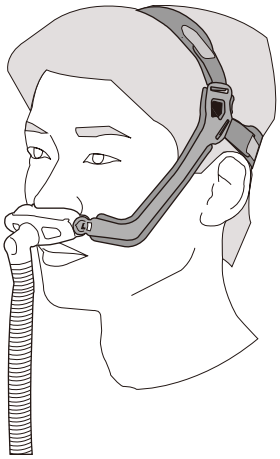
Adjust each end of the back strap (overtighting may cause excess pressure on upper lips).



Alternate the adjustment of headgear straps until they rest comfortably and rotate pillow sleeve assembly to adjust nasal pillows angle to ensure them sit comfortably inside your nostrils.



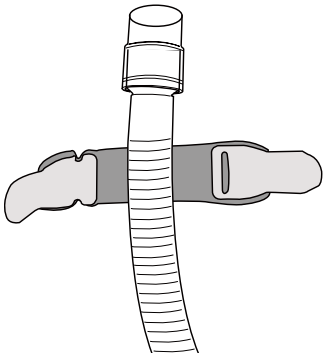
Connect one end of the main air tubing to your flow generator and the other end to the swivel. Turn your flow generator on.



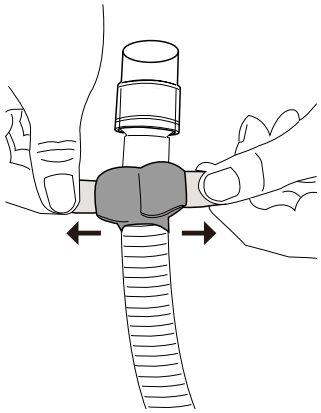
Take time to adjust the headgear straps, angle of the pillow assembly and position of the short tube assembly to achieve a secure and comfortable fit.

Note: Refer to your flow generator manual for details on setting and operational information.
If you feel air leak, readjust the angle of the nasal pillows to get a better seal. If you are unable to resolve any leaks, you may need an alternative pillow sleeve size.

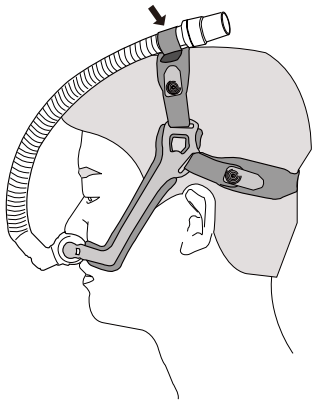
Using Tube Retainer (Optional)



Wrap tube retainer over the short tube. Make sure smooth surface sits outside.



Thread one end of the tube retainer into the gap of the other end.

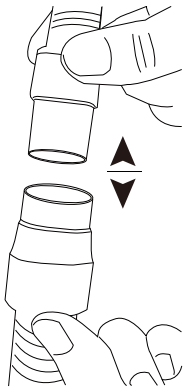


Attach both ends of the tube retainer onto the top strap.

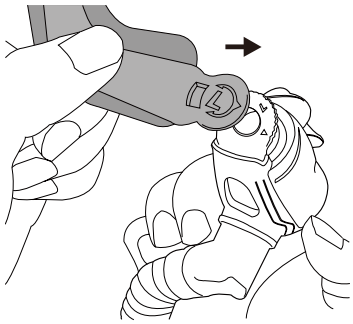
Removing the Willow™

To remove the Willow™, pull the pillow sleeve assembly away from your nose and lift the headgear off your head. You do not need to loosen the headgear straps.

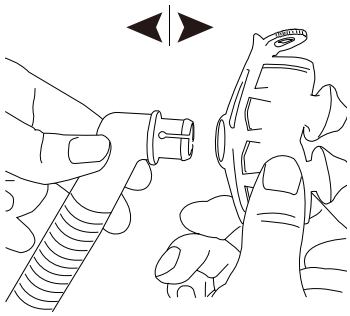
Disassembling for Cleaning



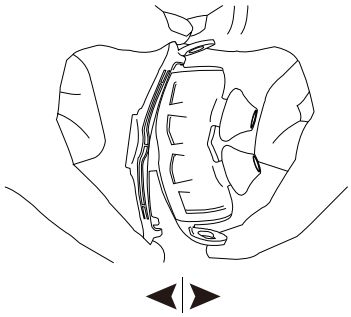
Disconnect the flow generator tubing. Hold the swivel and pull it away from the flow generator tubing.



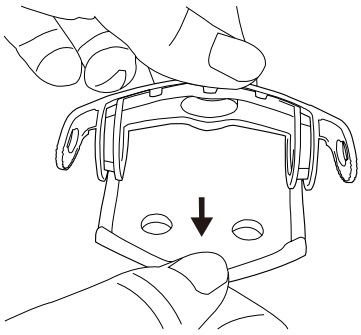
Detach the panels from the pillow sleeve assembly. Rotate the panel until the rectangular block lies in parallel with the gap in the frame. Simply pull the panels from the frame.



Detach the short tube assembly. To do this, hold the elbow and pull it away from the frame.



Remove clip from frame.



Disassemble the pillow sleeve assembly. To do this, detach the clip and peel the pillow sleeve off the frame.

Note: The short tube assembly cannot be taken apart.

CAUTION

- Do not pull on the short tube or the flow generator tubing as they may get damaged.
  To disassemble the Willow™ for daily cleaning, follow steps 1–3.
  To disassemble the Willow™ for weekly cleaning, follow steps 1–5.

Cleaning the Willow™ in the Home

Notes:

- *Wash your hands before cleaning the mask.*
- *Wash the headgear before first time use, as the dye may run. It is important to always handwash the headgear.*
- *The headgear may be washed without being disassembled.*

Daily

Handwash the pillow sleeve assembly, short tube assembly and cap in warm (approx. 30° C), soapy water for one minute. Use pure soap. Rinse the components well with drinking quality water and allow to air dry out of direct sunlight and heat.
Note: Ensure that the vent holes are not blocked. Use a soft bristle brush to clean the vent.

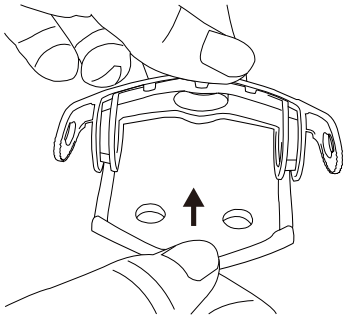
Weekly

Handwash the headgear and all components in warm,(approx. 30° C) and soapy water. Use pure soap. Rinse the components well and allow them to air dry out of direct sunlight.

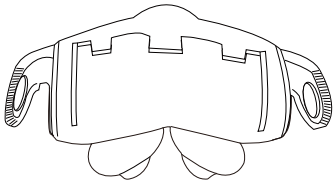
CAUTION

- Do not use solutions containing bleach, chlorine, alcohol, aromatics, moisturizers, antibacterial agents, or scented oils to clean any part of the system or air tubing. These solutions may cause damage and reduce the life of the product.
- Exposing any part of the system or tubing to direct sunlight or heat may cause deterioration.
- If any visible deterioration of a component is apparent (cracking, crazing, tears etc), the component should be discarded and replaced.

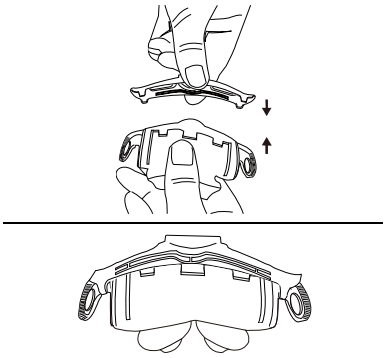
Reassembling the Willow™



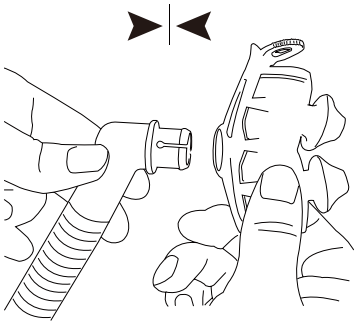
Wrap the pillow sleeve around the frame in the correct position. Make sure the nasal pillows are pointing upwards.



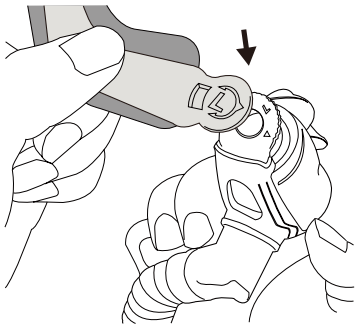
Insert the pillow sleeve edges into the groove of the frame. Make sure assemble it in the right side, or it can not be attached tightly to the frame.



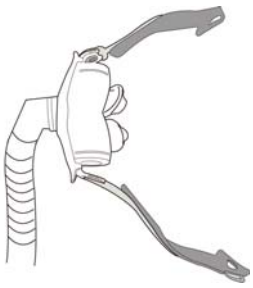
Hold the clip and align the circle in its middle with the one on the frame. Gently push the clip onto the frame to secure the pillow sleeve in place.



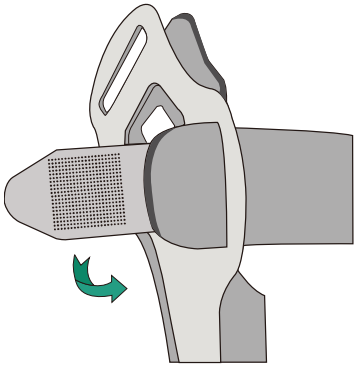
Attach the short tube assembly to the pillow sleeve assembly. To do this, push the elbow into the seal ring until it clicks into place.



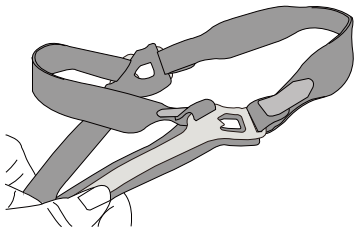
Check positioning markers on frame and panels are on the same side. Make sure the headgear panels are facing out.



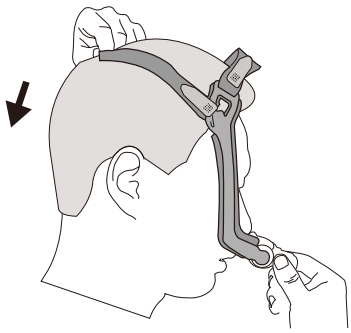
Attach the panels to the pillow sleeve assembly. To do this, insert the rectangular block at the smaller end of the panel into the headgear ring on the frame. Rotate the panel to a proper position. Fix the other panel in the same way.



Thread both ends of top strap and back strap through the gaps in the panels. Make sure rough surface of straps sits outside.



Fold back the straps over to secure.



Slip the headgear on your head and adjust the position.

Additional Information

Reassembling the Headgear

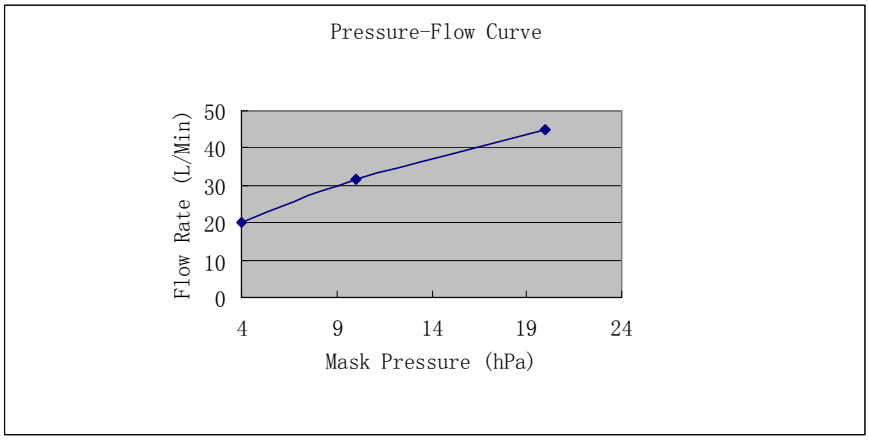
If taken apart, the headgear has four parts:

A: Left strap; B: Right strap; C: Back strap; D: Top strap.
The left and right straps are bond with two panels as their substrates, while the back and top straps are solely nylon material with two fibulas at each end. The top strap is shorter than the back one.
Thread the back strap and top strap through the gaps of the panels and fix them using the nylon fibulas.

Disposal

The Willow™ Nasal Pillows System does not contain any hazardous substances and may be disposed of with your normal household refuse.

Technical Specifications

Pressure–Flow Curve	
Dead Space Information	Dead space is the empty volume of the pillow sleeve and short tube assembly up to the swivel. The dead space of the Willow™ for all pillow sleeve sizes is 96 mL.
Therapy Pressure	4 to 20 hPa.
Resistance	Drop in pressure measured (average for three pillow sleeve sizes) at 50 L/min: 1.0 hPa at 100 L/min: 3.1 hPa.
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871 . The A-weighted sound power level of the mask is 26 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1m is 18 dBA, with uncertainty 3 dBA.
Environmental Conditions	Operating temperature: +5°C to +40°C Operating humidity: 10%–93 % relative humidity non-condensing Storage and transport: - 20°C to + 55°C Storage and transport humidity: 10%–93 % relative humidity non-condensing.

Symbols

System and Packaging

Caution, consult accompanying documents

LOT Lot number

User Guide

Indicates a Warning or Caution and alerts you to a possible injury or explains special measures for the safe and effective use of the device.

Limited Warranty

It is warranted that Willow™ Nasal Pillows System, including its components，frame, pillow sleeve, headgear, tubing and other accessories shall be free from defects in material and workmanship for a period of ninety (90) days from the date of purchase by the initial consumer.
To exercise the rights under this warranty, contact the local, authorized dealers or:

MANUFACTURER：
BMC MEDICAL CO., LTD.

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